

FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2691-2710

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *December 19, 1949.*

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**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

2691. Alleged misbranding of Penicillin Oil Vehicle with Wax and Penicillin Oil Vehicle. U. S. v. E. S. Miller Laboratories, Inc., and Ernest D. Reason. Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 25592. Sample Nos. 86452-H, 31225-K.)

INFORMATION FILED: December 10, 1948, Southern District of California, against E. S. Miller Laboratories, Inc., Los Angeles, Calif., and Ernest D. Reason, vice president and general manager of the corporation.

ALLEGED SHIPMENT: On or about April 7 and November 12, 1947, from the State of California into the States of Arizona and Colorado.

*For presence of a habit-forming narcotic without warning statement, see Nos. 2693-2695; omission of, or unsatisfactory, ingredients statements, No. 2696; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2692, 2694-2696; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2692, 2694-2696.

NATURE OF CHARGE: *Penicillin Oil Vehicle with Wax*. Misbranding, Section 502 (a), the following statements in the labeling "Sterile Oil Vehicle for Penicillin. A refined cholesterized cottonseed oil containing white wax 2% (W/V)," "Penicillin Oil Vehicle, a neutral cholesterized vegetable oil with 2% white wax," and "Penicillin Oil Vehicle (with wax) Penicillin Oil Vehicle is a neutral vegetable oil containing white wax 2% (W/V) and an absorption base which forms an emulsion with an aqueous solution of penicillin" were false and misleading. The statements represented and suggested that the article when used as a vehicle for penicillin, according to directions, namely, "Add only enough sterile distilled water to the penicillin to form a solution, usually 0.2 to 0.3 cc. are required. If the wax crystallizes out of the solution, warm the ampul in warm water to liquefy. Fill a syringe with the desired amount of the oil solution and empty it into the vial containing the penicillin solution. Shake well and a perfect easy flowing emulsion will result," would produce the same results as those produced by the penicillin in an oil wax base which is in common and general use by the medical profession, and which would in ordinary circumstances maintain the effective penicillin blood levels for a period of approximately 24 hours. The article when used as a vehicle for penicillin, according to the directions, would not produce the same results as those produced by penicillin in an oil wax base in common and general use since the article when mixed with penicillin, in accordance with the directions, would not maintain the effective penicillin blood levels for a period of approximately 24 hours but would maintain the effective penicillin blood levels for a much shorter period. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the extent to which the article would maintain effective penicillin blood levels, which fact was material in the light of the representations in the labeling which conveyed the impression that the article when used as directed, would produce penicillin in an oil wax base which is generally recognized as capable of prolonging the effective penicillin blood levels for a period of approximately 24 hours; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state the frequency with which penicillin in combination with the article should be injected.

Penicillin Oil Vehicle. Misbranding, Section 502 (a), the statements in the labeling "Penicillin Oil Vehicle. A neutral cholesterized vegetable oil," "Penicillin Oil Solvent," and "Penicillin Oil Solvent is a neutral vegetable oil containing an absorption base which forms an emulsion with an aqueous solution of penicillin" were false and misleading. The statements represented and suggested that the article when used as a vehicle for penicillin, according to directions, namely, "Add only enough sterile distilled water to the penicillin to form a solution, usually 0.2 to 0.3 cc. are required. Fill a syringe with the desired amount of oil and empty it into the vial containing the penicillin solution. Shake well and a perfect, easy flowing emulsion will result," would prolong the action of penicillin in the body. The article when used as a vehicle for penicillin, according to the directions, would not prolong the action of penicillin in the body. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the extent to which the article would maintain effective penicillin blood levels, which fact was material in the light of the representations in the labeling which conveyed the impression that the article when used as directed would prolong the action of penicillin in the body; and, Section 502 (f) (1), the labeling failed to bear adequate

directions for use since it failed to state the frequency with which penicillin in combination with the article should be injected.

DISPOSITION: February 19, 1949. Pleas of not guilty having been entered, the case came on for trial before the court without a jury on February 16, 1949. At the conclusion of the trial, the court returned a verdict of not guilty.

2692. Misbranding of benzedrine sulfate tablets and thyroid tablets. U. S. v. Ray's Pharmacy, Ray S. Gresham, and Ben B. Western. Pleas of nolo contendere. Fine of \$250 against pharmacy and \$125 against each individual. (F. D. C. No. 25323. Sample Nos. 26387-K, 27023-K.)

INFORMATION FILED: On or about November 9, 1948, Eastern District of Missouri, against Ray's Pharmacy, a partnership, Macon, Mo., and Ray S. Gresham and Ben B. Western, members of the partnership.

INTERSTATE SHIPMENT: On or about February 19 and 24, 1948, from Philadelphia, Pa., and Tuckahoe, N. Y., of quantities of *benzedrine sulfate tablets* and *thyroid tablets*.

LABEL, WHEN SHIPPED: "Benzedrine Sulfate Tablets [or "Thyroid, U. S. P. Compressed"] * * * Caution: to be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 26, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of tablets of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold to various persons without a prescription, which acts of the defendants resulted in the tablets being misbranded. The repackaged tablets were labeled "Rays Benzidrine Sulfate 5 Mg." and "B & W Thyroid 1 grain."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the boxes containing the repackaged tablets bore no labeling containing directions for use; Section 502 (b) (1), the label of the repackaged tablets bore no statements containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), the label of the repackaged tablets bore no statements of the quantity of the contents.

DISPOSITION: May 23, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the pharmacy and \$125 against each individual.

2693. Misbranding of seconal sodium pulvules. U. S. v. Keene Pharmacal Co. (Harold Lloyd's Prescriptions), and Harold A. Lloyd, John M. Hilsher, and Percy L. Stogsdill. Pleas of nolo contendere. Corporation fined \$200 on count 1 and total of \$500 on counts 2 to 6; payment of \$500 suspended and corporation placed on probation for 1 year. Each individual defendant fined \$100. (F. D. C. No. 25594. Sample Nos. 22376-K, 22378-K, 22379-K, 22381-K, 22384-K, 22386-K.)

INFORMATION FILED: January 26, 1949, Northern District of Texas, against the Keene Pharmacal Co., a corporation, commonly known as Harold Lloyd's Prescriptions, Dallas, Tex., and against Harold A. Lloyd, president of the corporation, and Percy L. Stogsdill and John M. Hilsher, pharmacists.

INTERSTATE SHIPMENT: Between the approximate dates of January 28 and February 14, 1948, from Indianapolis, Ind., to Dallas, Tex., of quantities of *seconal sodium pulvules*.